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From Usability Engineering to Evidence-based Usability in Health IT

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Abstract. Usability is a critical factor in the acceptance, safe use, and success of health IT. The User-Centred Design process is widely promoted to improve usability. However, this traditional case by case approach that is rooted in the sound understanding of users' needs is not sufficient to improve technologies' usability and prevent usability-induced use-errors that may harm patients. It should be enriched with empirical evidence. This evidence is on design elements (what are the most valuable design principles, and the worst usability mistakes), and on the usability evaluation methods (which combination of methods is most suitable in which context). To achieve this evidence, several steps must be fulfilled and challenges must be overcome. Some attempts to search evidence for designing elements of health IT and for usability evaluation methods exist and are summarized. A concrete instance of evidence-based usability design principles for medication-related alerting systems is briefly described.

Keywords. Usability, human engineering, medical informatics, health informatics, evaluation studies as topic, evidence.

1. Introduction

Studies on Human Factors and usability of Health Information Technology (health IT) are increasingly demonstrating their importance to health IT design, development and implementation [1]. Even if Human Factors and usability are often closely associated, they however do not refer exactly to the same discipline.

According to the International Ergonomics Association, "*Human Factors (or ergonomics) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance.*" [2]. Human Factors has a holistic view of the work system. This work system is "*comprised of five elements: the person performing different tasks with various tools and technologies in a physical environment under certain organizational conditions*" [3]. The "tool" (or product or technology) as a topic of research can be described by several characteristics amongst which is usability.

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Usability is then looked upon as "*the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specific context of use*" [4]. Usability thereby concerns the elements of the graphical user interface, their arrangement, navigational structures, the behaviour of the system in response to users' actions along with the completeness of functions and the work model implemented in the system [5]. Gradually, usability has become a research field in its own right but with the same theoretical, methodological, and empirical roots as Human Factors.

This contribution focuses on how usability research may lead to evidence-based usability practice in the field of health IT.

2. Why is it necessary to consider usability in health IT evaluation?

There are three main categories of reasons accounting for the growing importance of considering usability in the design and implementation of health IT.

2.1. Usage and safety of use reason

Usability is an intrinsic characteristic of a technology that impacts end-users' interaction with the technology; it leads to higher work efficiency in case of good usability, but in case of poor usability it may also slow down user performance, decrease users' satisfaction, and expose users to use errors [6;7]. Then, through its influence on the user, the usability of a technology will indirectly impact the other components of the work system in which this technology is implemented (incl. ensuring patient safety) and the whole work system performance [6-8]. Ultimately, usability flaws in a technology may (i) lead users to reject the technology and / or (ii) even cause harm to patients. [2] Case studies have identified usability flaws that have had consequences on the quality of the usage of the technology, and subsequently on the outcome of the usage.

For instance, a drop-down menu in a Computerized Physician Order Entry (CPOE) proposing 225 options for medical dosing frequency compels a physician to scroll through the whole list of options. This promoted errors especially for uncommon drug programs. Confused by apparently similar labels, the physician selected the wrong dosing frequency options. As a consequence, a patient received four times excess of Digoxin inducing ventricular fibrillation. Several studies showed that usability-induced use-errors led to patient harm or death: radiation over-dosage errors during radiotherapy [9], dispensing errors with pen injectors [10], or falsely implanted total knee arthroplasties [11]. These insights have led to a growing interest in the effect of the usability of a technology on the system use outcome.

2.2. Regulatory reason

The safety concern led the European Commission to reinforce the "ergonomics" essential requirement for CE marking: the EU revised Medical Device Directive

[2] See also: F. Magrabi et al., Health IT for patient safety and improving the safety of health IT, in: E. Ammenwerth, M. Rigby (eds.), Evidence-Based Health Informatics, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

(MDD) [12] explicitly requires a safety-oriented usability engineering process to be integrated in the design and development lifecycle of medical devices. In order to adhere to this directive, international standards suggest to implement the User Centred Design process (UCD) during the technology design and development lifecycle (e.g. [13]). Those regulations first dealt with medical devices, and then have been progressively extended to specific types of medical software (e.g. Clinical Decision Support System (CDSS)) [12]. Now, international committees recommend applying UCD to all types of medical systems (including software) (e.g. [1;14]).

2.3. Impact evaluation reason

Over the last decade, requirements over Health Technology Assessment including cost-benefit and medico-economic analyses have been increasing. As a consequence, more and more technologies are expected to undergo some sort of clinical investigation demonstrating their safety and positive clinical impact. However there is one major difference between clinical trials of drugs and clinical investigation studies of health IT and medical devices: the latter are user-dependent. Their efficacy and efficiency depends on their proper use by the end-users (clinicians or patients). When important usability flaws plague the human-machine interface of a product, besides potential erroneous use, users may adopt workaround behaviours to adapt to the poorly usable tool (e.g. [7]). Many of those behaviours are quite personalised and variable. This introduces major potential biases in clinical studies of health IT, as erroneous use, workarounds, and other adapting behaviours inevitably modify the technology efficacy and efficiency. Careful consideration of usability before and during clinical investigation of health technology may help uncover those hidden or intermediary variables and explain puzzling contradictory results [15].

3. Usability Engineering: the User-Centred Design Process

Health technologies should be designed following a safety-oriented UCD process [12;16] in order to ensure that the resulting product is (i) safe to use, (ii) compliant with regulations, and (iii) usable enough to be properly used by end-users, which is a major condition for the technology to achieve its intended (clinical and organisational) impact.

The UCD process is an iterative design and evaluation strategy that considers end-users (i.e. clinicians or patients) by taking into account their needs and by involving them in design and evaluation activities [4]. As described in Figure 1, this process includes four main iterative tasks that may be categorized into specification and evaluation activities.

3.1. Specification activities

First, a sound and precise analysis of the work system in which the technology is to be implemented has to be carried out, including the analysis of the cognitive tasks performed by the end-users [17]. Results depict the whole work system including work partners and the collective and collaborative aspects: needs of the end-users are deduced and potential room for improvement for the current work system is identified. The analysis also allows foreseeing how the technology will support the tasks to be

performed, fulfil users' needs and ultimately improve the work system's efficacy and efficiency. On this basis, specifications for the technology under design are formulated.

Once the context of use has been analyzed, a supplementary source of information, i.e. existing usability design principles, can be used to refine the specifications. Those principles gather knowledge on human capabilities and limitations in a given context. They are more or less generic/specific, some being applicable to any kind of technology and context of use (e.g. [18] for interactive systems), others to a unique type of technology (e.g. [19] for medical alerting systems). Those principles are no substitute for the work system analysis; they provide designers with complementary Human Factors information relevant for the technology under design. Recent studies have shown that applying usability design principles reduces user workload, improves the efficiency of technology, and increases user satisfaction [20].

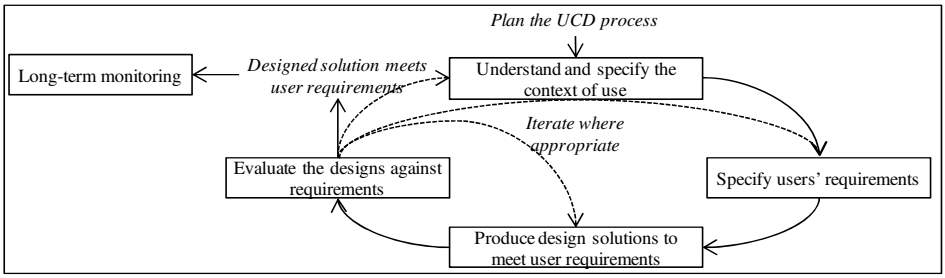

Figure 1. The User-Centred Design process adapted from the ISO 9241-210 [4].

3.2. Evaluation activities

Usability evaluation pursues two main purposes depending on the stage of the system development lifecycle they take place in [13]:

- **Formative usability evaluation** (or "usability verification") consists of iterative and fast evaluation rounds aiming at identifying and fixing usability flaws of the successive versions of the product under development. It applies to early mock-ups and prototypes up to the pre-final version of the product.
- **Summative usability evaluation** (or "usability validation") aims at validating the usability of the final version of the product before its release for clinical use.

Three types of usability evaluation methods are recommended by standards [4]:

- **Expert evaluations** are in-lab methods performed by usability experts without involvement of any end-users. Those methods include heuristic evaluation, where usability experts analyze a user interface by comparing it against a set of usability principles (e.g. [18]), and cognitive walkthrough, where experts step through a user interface for a task, note goals, actions, system responses and potential problems [21]. Those methods require three to five Human Factors experts working in parallel, and enable uncovering of a large number of flaws in a small amount of time. Those methods are part of a prospective approach of the usability: the evaluators' expertise offers insight on what usability problems users might face, in order to fix these problems before the technology is actually used. Experts must own a sound expertise in usability and also in the clinical activity supported by the technology under evaluation. To cope with the problem of clinical expertise of the

evaluators, usability experts sometimes perform the usability evaluation with a clinical expert.

- **User testing** and **simulation** methods involve observing representative end-users interacting with the technology while carrying out representative tasks. These methods are often carried out as controlled observations in which the behaviours and interactions of the users with the technology are recorded for detailed analysis [22]. They are also often associated with the "think-aloud" method that is considered as the gold standard providing the best insight on user's interaction [23], or with the eye-tracking method [24]. The main difference between user testing and simulation rests on the ecological validity of the evaluation environment: user testing takes place in an office or in a usability lab while simulation requires locating the study in real or realistic settings.[3] Both methods can be applied as soon as an interactive mock-up is available; however, due to the costs inherent to the simulation, it is better to perform simulation with (close to) a final product. In terms of results, those methods enable observation of users facing usability flaws and how those flaws impact the usage (including use errors) and the work system (including safety issues).
- **Post market surveillance** is the method with the higher possible fidelity. It enables gathering usability feedbacks once the technology is implemented and used. Data can be collected through direct observation, users' questionnaire or interview, or review of incidents reports [25]. Data collected provide information on usage problems and negative outcomes likely induced by usability flaws in the system. Unintended usage of the technology and workaround behaviours can also be observed. However, the complexity of the work system in which the system is implemented can make it difficult to determine how the usability of the system impacts users and clinical outcomes and which usability issues are root causes.

Those methods have their own specificities and are not equivalent in terms of detection power of usability issues and in terms of types of issues detected [26]. They are often combined together or with other methods (e.g. log analysis, focus groups) and their results are triangulated in order to get a more complete representation of the quality of the technology in terms of usability [27]. Although insights from pre implementation usability evaluations inform redesign of the system, post implementation study is then a necessary step in order to get information on the effectiveness of the pre implementation usability evaluations.

4. Grounding User Centred Design (UCD) in evidence

For several decades UCD has been promoted by reference books, scientific publications, standards and is now imposed by European Union regulation for medical devices and some types of health IT. There is no more need to advocate that carefully taking into account usability during the design process can be beneficial to the design of Health Technologies: it facilitates usage and contributes to fulfilling the medical intention while preventing use-errors leading to patient harm.

[3] See also: S. Jensen, Clinical simulation as an evaluation method in health informatics, in: E. Ammenwerth, M. Rigby (eds.), Evidence-Based Health Informatics, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

But recommending or imposing usability engineering (UCD) does not mean that it is actually applied to all medical devices and all health IT. Indeed, several recent publications report negative outcomes and patient harm due to usability issues in various types of health technology [9-11;28]. This shows that manufacturers do not (properly) apply UCD so as to decrease the risk of usability-induced use errors. One cause is that manufacturers do not understand how to apply properly UCD. In order to convince all stakeholders, it is necessary to go from an "artisanal" (on a case to case basis) approach towards a UCD grounded in empirical evidence. The evidence will allow drawing upon guidelines for applying the UCD efficiently for each type of health IT and context of use and at each step of the design process. The following sections describe how evidence-based usability knowledge can be produced along with a concrete instance of this knowledge.

4.1. Definition of evidence-based usability

By analogy to evidence-based medicine, evidence-based usability is defined as "*the conscientious, explicit and judicious use of current best evidence in making decisions in design of interactive systems in health care by applying usability engineering and usability design principles that have proven their value in practice*" [29]. This evidence deals with two main topics:

- The design elements of the technology: what are the usability design principles for a given type of technology for which positive value has been demonstrated in practice? What are the instances of usability flaws (violations of those principles) known for this technology (usability mistakes not to make) and what are their consequences on the user and the work system?
- The usability evaluation methods: which method(s) is (are) most suitable at each step of the design process and each type of technology? In which conditions of application are those methods the most efficient? Which combinations of methods have proven their value in practice?

Even if the awareness of designers and researchers in health IT on the need for evidence is increasing, evidence-based usability is still at its infancy. Several steps must be completed and challenges must be overcome to achieve this evidence.

4.2. Steps to get evidence-based usability

The steps to get evidence-based usability are not fundamentally different from those in Health Informatics[30] but some specificities must be pointed out:

- **Perform high quality evaluations**. The main stimulus for evidence is the result of usability and socio-technical evaluations of health IT: descriptions of usability flaws and of their consequences. To ensure the validity of those results, it is necessary to apply properly the right study design[4] and evaluation method taking precautions against potential biases[5].

[4] See also: C.R. Weir, Ensuring the quality of evidence: Using the best design to answer health IT questions, in: E. Ammenwerth, M. Rigby (eds.), Evidence-Based Health Informatics, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

[5] See also: J. Brender, Theoretical basis of health IT evaluation, in: ibid.

- **Report evaluations precisely and completely**. The descriptions of the technology evaluated, of the context of evaluation, and of the evaluation method must be reported exhaustively along with the whole set of usability results to allow later meta-analyses.[6]
- **Identify and gather relevant high quality studies.** Scientific publications must be considered. However, not all usability (and socio-technical) evaluations of health IT are published due to non-disclosure agreement and publication reporting biases. To improve the coverage of existing data, grey literature, users' feedbacks to manufacturers, and incidents reports databases (e.g. MAUDE [31]) should be examined too.[7] Descriptions of incidents may provide information on the consequences of usability flaws on the user and in terms of patient safety.
- **Extract relevant data**. Data must be extracted in a standardized way. Data may be quantitative (e.g. number of errors) but, most of the time, they are qualitative (e.g. description of the usability flaws). For qualitative data, it is necessary to pay the greatest attention to the extraction process to ensure reproducibility.
- **Compare and synthesize publications' findings**. Meta-analyses can be performed (e.g. by comparing the severity of usability flaws in different tools). To go a step further with qualitative data, qualitative comparison analyses should be used to identify the causal contribution of various conditions to an outcome of interest [32]: it allows establishing cause-consequences links between usability flaws, usage problems, and negative outcomes.
- **Learn lessons in terms of usability evidence**. The evidence must present the value of usability methods and design principles, and the conditions of validity of the results. Since one learns better from one's mistake, the evidence of the negative impact of violating usability design principles (i.e. usability flaws) or not applying properly usability evaluation methods must be presented too.
- **Disseminate evidence-based usability knowledge**. The evidence should be disseminated during the Health Informatics curriculum or through training of designers. Moreover, a database should be developed that would contain the formulation of the evidence along with the data supporting and contradicting it.[8]

4.3. Challenges to overcome

The road towards evidence-based usability is paved with challenges to be faced:

- **Uneven quality of evaluation**. Despite good practices guidelines [33][9], manufacturers favour quick and dirty methods (e.g. questionnaire targeting perceived usability) over validated methods (e.g. usability test). Providing evidence on the value of validated usability methods will promote their use.
- **Poor reporting quality**. Overall, usability studies on health IT are poorly reported [34] (e.g. not all usability issues are reported). Existing reporting guidelines [35][10] do not completely fit the specificities of usability evaluations (e.g. no mention of

[6] See also: C. Urquhart et al., Systematic reviews and meta-analysis of health IT, in: E. Ammenwerth, M. Rigby (eds.), Evidence-Based Health Informatics, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

[7] See also: F. Magrabi et al., Health IT for patient safety and improving the safety of health IT, in: ibid

[8] See also: A. Georgiou, Finding, appraising and interpreting the evidence, in: ibid.

[9] See also: P. Nykänen et al., Quality of health IT evaluations, in: ibid.

[10] See also: E. Ammenwerth et al., Publishing health IT evaluation studies, ibid.

the iterative process). Guidelines dedicated to Human Factors and usability [36] should be used. Similarly, incident reports lack details and are therefore difficult to interpret. Incident reporting forms should be structured so that usability characteristics of the technology incriminated are described precisely.

- **Lack of taxonomy**. Health IT lacks a recognized taxonomy. Consequently, labels of the technology evaluated may be subject to discussion (e.g. what does "medication-related CDSS" refer to: an alerting system, order sets, clinical reminders?). Therefore the scope of the evidence related to that technology may be confused.
- **Difficulties to identify usability studies**. "Usability" and "Human Factors" are not MeSH terms. This issue may bias the identification of usability studies. Moreover, usability evaluations are often part of larger studies that mention seldom "Usability" in the title, the keywords, or the abstract. Authors should be encouraged to explicitly identify usability activities in their paper.
- **Distinguish the origin of usability issues**. Usability issues may originate in features of the technology but also in the local setting of this technology. Telling this difference may be a difficult but is a crucial task in order not to attribute a usability issue to a feature of a product when it comes from its parameterization. Therefore, reports should highlight as far as possible the origin of the usability issues.
- **Difficulties to access manufacturers' databases**. Manufacturers do not share users' feedbacks and results of homemade usability evaluations with Human Factors researchers. This policy prevents researchers from accessing and analyzing large valuable repositories. A win-win cooperation mode should be defined to encourage manufacturers to share those data with the Human Factors community.

4.4. Examples for available evidence

This section describes the few available examples for evidence both on design elements and on the usability evaluation methods.

4.4.1. Evidence on design elements

Several reviews aimed at identifying the positive and negative usability characteristics of a given health IT. Those reviews focused on CPOE [37], Electronic Medical Records [38], medication-related alerting systems [5] and M-health applications [39]. Those reviews are not equally useful. Only the first three ones matched the usability flaws they identified with usability design principles. The review on M-health applications defined a list of usability characteristics generic to mobile applications, not specific to a type of application; moreover, its results mixed usability flaws, usage problems and design principles. Therefore, it is not possible to build directly evidence on the design elements for a specific type of mobile applications.

One example of a more structured review is [5] that identified the usability flaws of medication-related alerting systems and then complemented them (i) by an analysis of the consequences for the user and for the work system of those flaws [40] and (ii) by a matching with existing usability design principles [41]. Table 1 and Figure 2 present excerpts of the results from this review. Based on those results, a database could be provided to designers to make them aware (i) of the known usability mistakes and their

consequences to be prevented when designing a medication-related alerting system and (ii) of the existing usability design principles useful to prevent those mistakes.

Table 1. Excerpts from the database of usability issues related to medication alerting system (details in [41]).

Usability flaws	Usage problems	Negative outcomes	Related Usability Design Principles
#1 Compatibility, alert presentation issue: "CPOE provides feedback on drug allergies, but only after medications are ordered."[7]	**Behavioural issue:** "Some house staff ignored allergy notices (…) and, most important, post hoc timing of allergy information." [7]	**Workflow issue:** "House staff claimed post hoc alerts unintentionally encourage house staff to rely on pharmacists for drug allergy checks, implicitly shifting responsibility to pharmacists." [7]	**Fit the clinicians' workflow**.: Alert must be displayed at the appropriate time during the decision making. [42]
#2 Insufficient guidance: "Physician (MD) orders [VA] aspirin - 162 mg. An order check [alert] appears. Says duplicate drug order. Non-VA ASPIRIN. [Alert] mentions 325mg. MD is looking at it also and [appears] confused"[43]	**Behavioural issue:** "MD clicks through [the alert] [accepts order]" [accepts without understanding the alert] [43]	**Patient safety issue:** "MD goes back to the medication list. Aspirin is now listed both under VA list and non-VA medication list" [double order of aspirin] [43]	Provide "**means to advise, orient, inform, instruct, and guide the users** throughout their interactions with a computer, including from a lexical point of view." [18]

In summary, existing reviews may provide the basis for evidence for design elements of health IT but the work is still to be up-dated and completed. As for other potential sources of evidence, there is still no in-depth analysis of incident reports that identify the positive and negative usability characteristics of health IT.

4.4.2. Evidence on usability evaluation methods

Some publications systematically analyzed the usability methods used for health IT. Most of them draw a picture of the type of usability methods used to develop and evaluate health IT [34], according to the stage of the System Development Life Cycle and the type of technology evaluated [44], or for a specific type of technology ("technology-based diabetes intervention platform" [45]). One specific study showed interest in the advantages and problems of usability evaluation methods applied to health collaborative systems [46]. Finally, the impact of usability evaluation and subsequent redesign on the task-completion time has also been evaluated [47]: the results of this review pointed towards a trend in improved task efficiency after modifications based on the results from usability evaluation.

In summary, the evidence published on usability evaluation methods is still weak (mostly lists of methods used) and a long road still needs to be travelled to be able to know (i) amongst all the existing ways to instantiate a specific method, which one is the most efficient for a given technology at each specific step of the design process, and (ii) whether some methods (and combinations of methods) are best suitable for a given technology and for specific parts of the UCD than others.

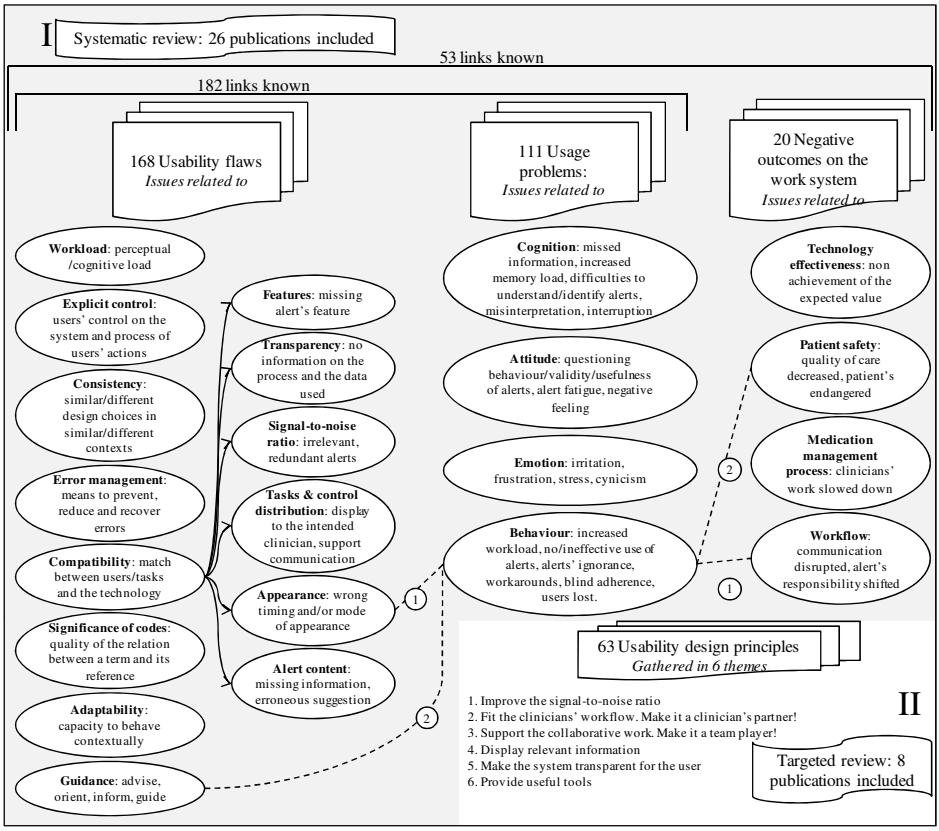

Figure 2. Representation (I) of the types of usability flaws reported for medication alerting systems and of their consequences for the user (usage problems) and the work system (negative outcomes); and (II) of the main themes of usability design principles known for that technology (based on [41]). Dotted lines synthesize two instances of cause-consequences chains reported in the literature between usability flaws in the alerting system, usage problems experienced by the users and negative outcomes in the work system (cf. Table 1).

5. Discussion

In this contribution we elucidate on usability as a critical factor of success and safe use of health IT. The UCD approach should be applied to ensure easy-to-use, efficient, satisfying, and non error-prone technology. Currently, stakeholders in the application of UCD do not apply UCD for it to be efficient for each type of technology and at each step of the design process. Therefore it is still possible to apply UCD erroneously and design technologies that can induce use-errors due to low usability. Guidelines based on empirical evidence are thus needed to help designers or evaluators avoid design flaws by choosing appropriate usability design principles and (combinations of) usability evaluation methods which usefulness and efficiency have been proven empirically.

Some attempts to get evidence-based usability knowledge exist. They proceed through systematic searching, critical appraisal and synthesis of the usability literature. Even if those attempts are limited, they are nonetheless valuable and provide the first

steps towards evidence-based usability practice. However, the road towards evidence-based usability is full of pitfalls. Measures must be adopted to help search for evidence.

Developing evidence-based usability knowledge is not an end in itself. It is necessary to make it available to designers and evaluators to ultimately improve health IT usability and to avoid usability-induced use errors, and thus to protect patients, users, and organisations. Thereupon, several questions must still be discussed: for instance, to whom precisely must the evidence be provided? Under which format? When in the project time-line? How generic or technology- or context-specific should the evidence be? The challenges to get evidence and the questions to discuss cannot be overcome and answered by individuals. Achieving and spreading evidence require the active involvement of the whole Human Factors and usability community in Health Informatics along with the support of manufacturers.

Recommended further readings

1. B. Séroussi, M.-C. Jaulent, C.U. Lehmann, editors, *Yearbook of medical informatics 2013: Evidence-based health informatics*, Stuttgart, Schattauer, 2013.
2. G. Salvendy, editor, *Handbook of Human Factors and Ergonomics*, 4th ed., John Wiley and Sons, Hoboken, New Jersey, 2012.
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Food for thought

1. Should formative and summative evaluations results be considered equally when searching for evidence on Human Factors and usability?
2. How do in-lab and field studies differ in providing sight on usability knowledge?
3. What metrics would ensure that usability actually improves or reduces the safety and the beneficial effect of a health technology?
4. What policy and institutional processes should become normative requirements to ensure that systems are developed in user-friendly formats?

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